Case Study | Regulatory Consulting

It is not surprising for companies to be confused when confronted by the regulatory maze that lay before them.

This is why many rely on MDC Associates for expert guidance.

FDA/ISO Regulatory Consulting Services

More and more companies requiring FDA clearance or compliance turn to MDC Associates for expert guidance. With so much at stake with a product launch or maintaining regulatory requirements for existing products, it makes sense to navigate the rigorous regulatory maze with a company that has successfully done it for over 25 years.

Companies should never attempt to navigate the regulatory maze alone. They must turn to an expert like MDC Associates for direction.

When companies need assistance with FDA clearance or compliance issues, most rest easier after turning to the experts at MDC Associates. Small wonder since outsourcing regulatory needs requires an elevated level of trust in a partner who can demonstrate a proven track record of success.

The expertise and experience that MDC Associates brings to the table gives clients the confidence and assurance that all their regulatory obligations are being met. The success that clients enjoy can be attributed to the expert regulatory and quality system consulting services offered by MDC Associates.

They include, but are not limited to the three-tier approach MDC Associates takes when providing expert guidance.

Three-tier approach

MDC Associates takes an effective three-tier approach, which consists of:

One – putting into place quality systems in accordance with FDA QSR, cGMP and ISO 13485 requirements.

Two – planning and monitoring clinical trials, and

Three – providing all the support and guidance necessary to move through the entire regulatory review process

MDC Associates has the experience to offer a complete menu of regulatory and quality systems consulting services

- Register company with FDA
- Prepare facility and documentation required for FDA, QSR, cGMP, CMDCAS, MDD, IVDD and ISO compliance
- Monitor quality systems for continual regulatory compliance
- Develop and conduct regulatory training programs
- Develop clinical and analytical study protocols
- Conduct clinical trials
- Prepare pre-market submissions
- Conduct facility audits
- Provide aftermarket product service and support

Regulatory obligations being met

MDC Associates prepares on average five to ten FDA pre-market submissions per year. All have been cleared by the FDA, and have benefited from an average time to product approval of 80-120 days.

Besides obtaining clearance for professional products such as medical devices, MDC Associates has conducted clinical trials for clients selling Over-the-Counter (OTC) products, and successfully obtained FDA clearance for these products.

Of equal importance, MDC has guided several companies successfully through the process of obtaining CLIA waived status.

Whatever regulatory needs companies have, they can be assured that the professional and knowledgeable staff at MDC Associates is prepared to take the time to answer all of their questions or concerns

In addition to its proven track record of helping clients navigate the regulatory maze, MDC Associates also offers companies other specialized services

Call Center

MDC Associates' Call Center services and expertise of its staff save clients time, resources and money, and help head off issues before they trigger possible product recalls or other regulatory actions.

Market Research

MDC Associates' highly targeted and reasonably priced approach to Market Research enables clients to make sense of and capitalize on the many forces at work in their ever-changing and complex markets.

MDC

Our exeperience ensures your success.

MDC Associates, LLC
180 Cabot Street
Beverly, MA 01915

800-316-8585
email:fran@mdcassoc.com
www.mdcassoc.com